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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/717,990	HEIRLER, HORST	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8-20* is/are rejected.

7)☒ Claim(s) *1 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6 and 8-20 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed January 29, 2007 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1, 3-6 and 8-20 are pending and under examination. Claim 20 is newly added.

Applicant's arguments, filed January 29, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claim 1 is objected to for failing to consistently set forth the name of component (d) of the composition. Present claim 1 recites "alpha-linoleic acid", wherein the original claims recited "alpha-**linolenic** acid".

Claim 12 is objected to for failing to recite a comma between "D" and "E" in line 2 of the claim.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present claim 11 is directed to the inclusion of additional components into the fat phase of the claimed composition for administration to a diabetic subject, including "flavorings which are suitably spicy and anti-oxidative with regard to unsaturated fatty acids."

In particular, the specification as originally filed fails to provide adequate written support for the claimed genus of flavorings that are suitably spicy and anti-oxidative with regard to unsaturated fatty acids (claim 11).

Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties, aside from the express identification of rosemary extract, that would provide adequate written description of the genus of flavorings which are suitably spicy and anti-oxidative with regard to unsaturated fatty acids that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the present invention.

Applicant's specification states at paragraph [0031] of page 9, "Preferably, the fat phase of the composition for the use of the invention contains, apart from the components described above, in addition as emulsifiers, mono- and diglycerides from edible fatty acids (MDG such as e.g. E 471), but no phosphatides such as lecithin, which occur as natural emulsifiers, for example as side products during purification. In addition, there are fat-soluble vitamins, preferably the vitamins A, D, E and/or vitamin C in the form of ascorbyl palmitate, beta-carotin, butter and/or – with regard to highly-unsaturated fatty acid – suitably spicy flavorings such as e.g. rosemary extracts."

Such disclosure, while noted, fails to identify any compounds that would be considered within the

scope of the genus of flavorings that are suitably spicy and anti-oxidative with regard to unsaturated fatty acids. Applicant has failed to provide any limiting definition, or any chemical or physical characteristics of these compounds that are related to its function as an anti-oxidant such that one of ordinary skill in the art would have been able to readily identify the scope of those flavorings encompassed by the claimed genus.

MPEP §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus." Please reference *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The instant specification fails to define any structural component, such as a common core structural element, as being responsible for the function of the compound in acting as an antioxidant and, thus, has failed to define the metes and bounds of the genus. While it is duly noted that the genus of flavorings that are suitably spicy and antioxidative is clearly limited to those capable of functioning in either manner, it remains that Applicant has not appropriate defined the metes and bounds of the genus, even when limited by function (step-plus-function form). MPEP §2163 teaches that step-plus-function claims are adequately described if "the written description *adequately links or associates adequately described particular structure*, material, or acts *to the function recited in a step-plus-function claim limitation*," or if "it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a step-plus-function limitation." The instant application does not meet these criteria. The present specification provides no disclosure beyond the generic disclosure of the required function and rosemary extract that would provide a means

for identifying the compounds that would have been amenable for use in the present invention, nor does it specifically teach a common structural element that performs the function recited in the claim and would be readily identifiable to one of skill in the art. Furthermore, it has been held that a wish or plan for obtaining the invention as claimed does not provide adequate written description of an invention. Rather, a precise definition, such as by structure, formula, chemical name or physical properties or a combination thereof, is required. Please reference, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for claim limitations must arise from either an explicit or implicit suggestion by the disclosure to show that such a concept as claimed was actually in possession of Applicant at the time of the invention. For the reasons provided *supra*, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the genus of "flavorings which are suitably spicy and antioxidative with regard to unsaturated fatty acids."

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 11 is directed to the inclusion of additional components into the fat phase of the claimed composition for administration to a diabetic subject, including "flavorings which are suitably spicy and anti-oxidative with regard to unsaturated fatty acids."

In particular, the phrase "suitably spicy" is a relative term that renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and how one would determine whether the degree of spiciness was, in fact, "suitable", and for what it would be suitable. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, it is noted that spiciness is a subjective determination that varies per individual such that what one person may consider "spicy" may not be considered "spicy" by another.

Additionally, the purpose of the phrase "with regard to unsaturated fatty acids" in the claim limitation "flavorings which are suitably spicy and antioxidative with regard to unsaturated fatty acids" is unclear. For example, are the flavorings intended to be "spicy" when compared to the taste of an unsaturated fatty acid? Are the flavorings intended to have a greater antioxidative effect than an unsaturated fatty acid? Are the flavorings intended to be spicy and antioxidative if an unsaturated fatty acid is present in the composition? Are the flavorings intended to be spicy and antioxidative to camouflage the taste of an unsaturated fatty acid? In other words, the intent of the phrase "with regard to unsaturated fatty acids" in limiting the claim has not been clearly set forth and, accordingly, fails to reasonably apprise one of ordinary skill in the art at the time of the invention of the subject matter for which Applicant is seeking protection.

For these reasons, claims 11-13 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that present claim 13 recites the limitation "1 to 5 μg (40-200 I.U.) vitamin D3" (lines 1-2) and present claim 17 recites the limitation " 0.007 to 0.070 g niacin (nicotine amide)". The recitation of the parenthetical limitation(s) renders the scope of the claims indefinite because Applicant has failed to delineate how such limitations are intended to limit the claim. Though the limitations provided in the parentheses may be intended to circumscribe an equivalent dosage amount or an additional name for the same compound, it is unclear whether the parenthetical recitation of these terms is intended to simply make reference to an equivalent dosage amount or a preferable dosage amount or whether it is simply to make reference to another known name for that same compound, or whether such limitations are intended to limit the claim in another manner. In other words, the limiting effect of the claimed parenthetical limitations is not clearly set forth in the claims and, thus, fails to reasonably apprise one of ordinary skill in the art the metes and bounds of the subject matter for which Applicant is seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and, thus, are properly rejected.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only), cited to show a fact.

Alexander et al. teaches an enteral composition for providing nutrition or nutritional supplementation to a diabetic patient (abstract; p.2, l. 25-26) that reduces the sensitivity to dose and timing of insulin to reduce the post-prandial serum glucose via improved tolerance, metabolic and glucose management and insulin requirements (p.3, l.55-58), which contains: (1) a fat source comprising medium chain triglycerides (20% of the fat source) and long chain triglycerides, which are preferably provided as, e.g., hi-oleic safflower oil or hi-oleic sunflower oil, of which such oils further provide for the essential fatty acids linoleic acid and linolenic acid in an amount of 4-10% (p.4, l.10-26), (2) mono-unsaturated fatty acids (p.4, l.29-34), (3) a protein component (p.4, l.34-35), (4) a carbohydrate component (p.4, l.36-40), (5) flavoring, i.e., vanilla (Table, p.6), and (6) various vitamins and minerals, including vitamin A, beta-carotene, vitamin D, vitamin E, vitamin C, folic acid, vitamin B6, vitamin B12, thiamine (i.e., vitamin B1), riboflavin (i.e., vitamin B2), niacin, zinc, chromium, or manganese (Table, p.6-7). Alexander et al. teaches the use of water for formulating the disclosed product (Table, p.7).

Brenna (abstract) is cited to show that alpha-linolenic acid is an omega-3 fatty acid precursor that is converted into the omega-3 long-chain polyunsaturated fatty acid docosahexaenoic acid and/or eicosapentaen acid. Though docosahexaen acid and/or eicosapentaen acid is not explicitly taught by Alexander et al., the art recognized such acids as conversion products of alpha-linolenic acid and, therefore, such acids are necessarily present by the teaching of plant oils that contain linolenic acid.

The explanation of an effect or a previously unrecognized benefit of a specific amount of an active compound, i.e., in the instant case, the 10-30% medium chain triglyceride component that is effective to regulate and normalize fat metabolism in a subject, cannot confer novelty on a known process

when the skilled artisan was already aware of the occurrence of the desired therapeutic effect in supplementing the diet of a diabetic subject using an identical amount of medium chain triglycerides (i.e., 20%). Furthermore, the administration of a composition identical to that being administered in the present claims in the same amount to an identical subject necessarily has the same claimed effect in regulating and normalizing fat metabolism in a diabetic subject, whether such a property was recognized by the patentee or not. An identical product in an identical amount cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference MPEP §2112.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only), cited to show a fact.

Alexander et al. teaches an enteral composition for providing nutrition or nutritional supplementation to a diabetic patient (abstract; p.2, l. 25-26) that reduces the sensitivity to dose and timing of insulin to reduce the post-prandial serum glucose via improved tolerance, metabolic and glucose management and insulin requirements (p.3, l.55-58), which contains: (1) a fat source comprising medium chain triglycerides (20% of the fat source) and long chain triglycerides, which are preferably provided as, e.g., hi-oleic safflower oil or hi-oleic sunflower oil, of which such oils further provide for essentially fatty

acids linoleic acid and linolenic acid in an amount of 4-10% (p.4, l.10-26), (2) mono-unsaturated fatty acids (p.4, l.29-34), (3) a protein component (p.4, l.34-35), (4) a carbohydrate component (p.4, l.36-40), (5) flavoring, i.e., vanilla (Table, p.6), and (6) various vitamins and minerals, including vitamin A, beta-carotene, vitamin D, vitamin E, vitamin C, folic acid, vitamin B6, vitamin B12, thiamine (i.e., vitamin B1), riboflavin (i.e., vitamin B2), niacin, zinc, chromium, or manganese (Table, p.6-7). Alexander et al. teaches the use of water for formulating the disclosed product (Table, p.7).

Brenna (abstract) is cited to show that alpha-linolenic acid is an omega-3 fatty acid precursor that is converted into the omega-3 long-chain polyunsaturated fatty acid docosahexaenoic acid and/or eicosapentaen acid. Though docosahexaen acid and/or eicosapentaen acid is not explicitly taught by Alexander et al., the art recognized such acids as conversion products of alpha-linolenic acid and, therefore, such acids are necessarily present by the teaching of plant oils that contain linolenic acid.

The explanation of an effect or a previously unrecognized benefit of a specific amount of an active compound, i.e., in the instant case, the 10-30% medium chain triglyceride component that is effective to regulate and normalize fat metabolism in a subject, cannot confer novelty on a known process when the skilled artisan was already aware of the occurrence of the desired therapeutic effect in supplementing the diet of a diabetic subject using an identical amount of medium chain triglycerides (i.e., 20%). Furthermore, the administration of a composition identical to that being administered in the present claims in the same amount to an identical subject necessarily has the same claimed effect in regulating and normalizing fat metabolism in a diabetic subject, whether such a property was recognized by the patentee or not. An identical product in an identical amount cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference MPEP §2112.

Regarding the claimed amounts of medium-chain triglycerides (10-30%) versus saturated long-chain triglycerides (0.5-6%) (see, e.g., present claim 9), one of ordinary skill in the art would have found

it *prima facie* obvious to increase the amount of medium chain triglycerides (MCTs) relative to the amount of long-chain triglycerides (LCTs; i.e., reduce the amount of LCTs) because, as Alexander et al. explicitly teaches, MCTs aid in digestion; digestion of MCTs is easier than LCTs because LCTs are digested by various lipases that are not required to digest MCTs; absorption of MCTs is faster than LCTs because LCTs require incorporation into chylomicrons by intestinal mucosal cells; and LCTs are oxidized more slowly and require carnitine for entry into the mitochondria (p.4, l.16-20). Such a person would have been clearly motivated to do so in order to reduce the elapsed time from administration to therapeutic effect in the patient being treated so as to provide rapid nutritional supplementation.

Further, Alexander et al. teaches formulation of the disclosed product in a water vehicle, which is clearly indicative of the fact that the overall enteral formulation would, at least prior to mixing, necessarily have a fat phase containing the fat source(s) and an aqueous phase containing the water solvent. Accordingly, though Alexander et al. does not explicitly acknowledge such a characteristic of the disclosed formulation, such a property is considered to be necessarily present, absent factual evidence to the contrary. Moreover, it logically follows, and would have been readily apparent to the skilled artisan, that the presence of various fat-soluble and water-soluble vitamins and minerals would necessarily mean that each would be found in the phase in which they were soluble, e.g., the fat-soluble vitamin A would be found in the fat-phase, whereas the water-soluble vitamin B6 would be found in the aqueous water phase. The determination of the optimal ratio of fat phase to water phase (i.e., fat=80%, aqueous=20% or fat=60-65%, aqueous=35-40%) would have been directly dependent on the amount of fat necessary to treat the patient and the amount of water needed to prepare the formulation and maintain the desired osmolality of the solution. Accordingly, the ratio of fat phase to aqueous phase would have been reasonably expected to vary widely by individual to be treated and, in the absence of evidence to the contrary, the currently claimed ratios are not seen to be inconsistent with those that would have been determined by, well within the skill of and, therefore, *prima facie* obvious to, the skilled artisan.

Regarding the claimed dosage amounts of the various vitamins and minerals, the determination of the optimum dosage amounts of the presently claimed active components would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the dietary needs of the patient being treated. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentrations of the active ingredients are result-effective variables, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable ranges would have been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1, 3-6, 8-10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only), cited to show a fact, in view of Madigan et al. ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care*, 23:1472-1477; 2000),

Heine et al. ("Linoleic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr*, 1989 Mar; 49(3):448-456; Abstract Only) and The Merck Index ("Citric Acid", Monograph 2328, 1989; page 363).

Alexander et al. and Brenna as applied above.

Heine et al. teaches that linoleic acid-enriched diets in patients with non-insulin dependent diabetes causes a less atherogenic lipoprotein profile, but does not influence glycemic control and carbohydrate tolerance (abstract).

Madigan et al. teaches a comparative study of subjects suffering from Type 2 diabetes, wherein one cohort of patients was treated with a linoleic acid-rich diet and another cohort of patients was treated with an oleic acid-rich olive oil diet (abstract). Madigan et al. teaches that the Type 2 diabetes patients fed a linoleic acid-rich diet had higher fasting blood glucose and insulin levels, higher plasma cholesterol and LDL cholesterol and higher fasting and postprandial chylomicron and VLDL apoB48 and apoB100 than those fed an oleic-acid rich diet. Madigan et al. teaches that the decrease in the number of chylomicron remnant particles in those subjects fed an oleic acid-rich diet may reduce the risk of atherosclerosis (abstract).

In view of such teachings, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to use linoleic acid as a major component (i.e., 10-35%) of the disclosed diabetic supplement composition. Such a person would have been motivated to do so because linoleic acid-rich diets were known to exert an anti-atherosclerotic effect in patients suffering from Type 2 diabetes, which was a known, and deadly, complication of Type 2 diabetes. The skilled artisan would have incorporated linoleic acid with the reasonable expectation of success that the addition of such an acid in such a quantity would have conferred such an anti-atherosclerotic property to the composition.

Furthermore, one of ordinary skill in the art at the time of the invention would have also found it

prima facie obvious to also add oleic acid in a significant quantity of the total composition (i.e., 20-60%) of the disclosed diabetic supplement because oleic acid-rich diets were also known to reduce atherogenic risk in a manner similar to linoleic acid-rich diets. The very fact that both linoleic acid-rich diets and oleic-acid rich diets were known to have the same therapeutic effect of reducing atherogenic risk in patients with Type 2 diabetes raises the reasonable expectation of success that the two acids, when combined, would have, at minimum, additive, if not synergistic, effect in reducing atherogenic risk in diabetic patients when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Moreover, one would also have been motivated to provide more oleic acid than linoleic acid because oleic acid was known in the art to have an additional therapeutic benefit over linoleic acid, namely, that oleic acid was known to reduce atherogenic risk *and* also reduce blood glucose and insulin levels, where linoleic acid was only known to be capable of reducing atherogenic risk in the absence of any effect on glycemic control or carbohydrate tolerance. Accordingly, the inclusion of oleic acid in greater quantity than linoleic acid would have been reasonably expected to increase the anti-atherosclerotic properties of the composition, as well as to assist the diabetic patient in maintaining proper glycemic control.

Regarding the specifically claimed ranges of linoleic acid and oleic acid (10-35% and 20-60%, respectively), it is further noted that the determination of the optimum dosage amounts of the presently claimed active components would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the

age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the dietary needs of the patient being treated. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentrations of the active ingredients are result-effective variables, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable ranges would have been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Lastly, one of ordinary skill in the art would have found it *prima facie* obvious to incorporate citric acid into the disclosed diabetic supplement because, as taught by The Merck Index, citric acid is a commonly used acidulant for pH adjustment and also to enhance flavor. Such a person would have been motivated to do so in order to arrive at a pharmaceutically acceptable pH value and also to enhance the palatability of the composition.

Conclusion

Rejection of claims 1, 3-6 and 8-20 is proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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April 24, 2007

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